Evidence for Better Lives Study

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Evidence for Better Lives Study: a comparative birth-cohort study on child exposure to violence and other adversities in eight low- and middle-income countries - foundational research (study protocol)

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ABSTRACT

Introduction Violence against children is a health, human rights and social problem affecting approximately half of the world's children. Its effects begin at prenatal stages with long-lasting impacts on later health and well-being. The *Evidence for Better Lives Study* (EBLS) aims to produce high-quality longitudinal data from cities in eight low- and middle-income countries—Ghana, Jamaica, Pakistan, the Philippines, Romania, South Africa, Sri Lanka and Vietnam—to support effective intervention to reduce violence against children. EBLS-Foundational Research (EBLS-FR) tests critical aspects of the planned EBLS, including participant recruitment and retention, data collection and analysis. Alongside epidemiological estimates of levels and predictors of exposure to violence and adversity during pregnancy, we plan to explore mechanisms that may link exposure to violence to mothers' biological stress markers and subjective well-being.

Methods and analyses EBLS-FR is a short longitudinal study with a sample of 1200 pregnant women. Data are collected during the last trimester of pregnancy and 2 to 6 months after birth. The questionnaire for participating women has been translated into nine languages. Measures obtained from mothers will include, among others, mental and physical health, attitudes to corporal punishment, adverse childhood experiences, prenatal intimate partner violence, substance use and social/community support. Hair and dry blood spot samples are collected from the pregnant women to measure stress markers. To explore research participation among fathers, EBLS-FR is recruiting 300 fathers in the Philippines and Sri Lanka.

Ethics and dissemination The study received ethical approvals at all recruiting sites and universities in the project. Results will be disseminated through journal publications, conferences and seminar presentations involving local communities, health services and other stakeholders. Findings from this work will help to adjust the subsequent stages of the EBLS project.

Strengths and limitations of this study

- ► The study is designed to inform a large-scale, birth cohort study in eight cities across the world.
- ► Evaluating training materials and tools developed will allow refinements and improvements for the large-scale study.
- ► The study will enhance engagement with policymakers, community members and other stakeholders to support efforts to address violence against children in all study sites.
- ► Data collection uses similar procedures to collect comparable data on exposure to violence.
- ► Participants are selected using a non-probabilistic sampling strategy. The generalisation to the broader underlying population is limited.

INTRODUCTION

Around half of children worldwide experience some form of interpersonal violence.[1] Exposure to violence interferes with children's neurological and socio-emotional development, contributes to lasting behavioural problems and has lifelong effects on well-being, health and productivity.[1–4] While the negative impact of violence has been extensively documented, less is known about the effect of prenatal intimate partner violence (p-IPV) on early child development. Recent research suggests that exposure to IPV during the prenatal period is linked to a number of

morbidities such as low birth weight, preterm delivery[5] and other indices of poor fetal health.[6–9] While the mechanisms explaining these outcomes remain unclear, multiple possible pathways linking p-IPV with child development outcomes have been suggested. These include mental illness, substance use, healthcare under-utilisation, poor emotional attachment to the fetus, maternal stress, systemic inflammation and the regulation of specific genes relevant to, for example, the functioning of the hypothalamic-pituitary-adrenal (HPA) axis.[10 11] Research in humans and other mammals suggests that exposure to dangerous levels of cortisol can have long-lasting impact on multiple areas of the brain, affecting, for instance, the child memory, verbal IQ and behaviour.[9 12]

Evidence-based preventive policies are known to contribute to the reduction of violence against children.[13] However, to date, most research into violence during the first years of children's lives has been conducted using cross-sectional, retrospective designs in affluent societies.[14 15] Little is known from low- and middle-income countries (LMICs), where most of the world's children live and where resources to address these problems are limited.[1 16]

In this context, the *Evidence for Better Lives Study* (EBLS) aims to produce high-quality evidence from non-western societies to support effective strategies to reduce violence against children from pregnancy onwards. It involves an interdisciplinary policy impact and capacity-building programme of longitudinal research based in eight cities chosen to reflect the diversity of cultural, social and economic conditions across the globe. EBLS is an ambitious research programme developed in four main stages (figure 1), including an initial scoping exercise (December 2015), a feasibility study (October 2016 to March 2018), the current foundational research (July 2018 to December 2019) and a full study expected to start in 2020. While the first two stages helped to articulate the aims of the project and to select the study sites, EBLS-FR tests the main components for the full study (eg, recruitment, data collection instruments, translations).

Four features make EBLS-Foundational Research a significant advance on previous studies. First, it recruits pregnant women in the third trimester of pregnancy, measuring prenatal exposures to violence and other adversities when they are happening and thereby overcoming the limitations of using retrospective recall.[17 18]

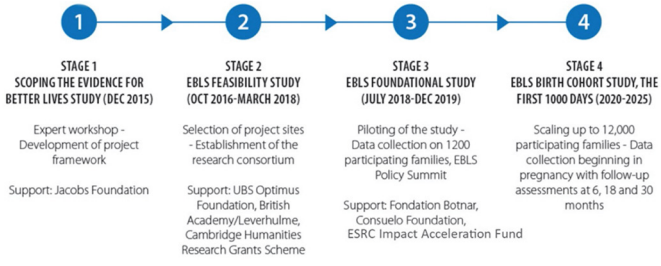

Figure 1 The four main stages of Evidence for Better Lives Study (EBLS).

Second, the longitudinal design of the study allows researchers to collect information on the same families over time, a method that is uniquely well placed to illuminate issues that affect children's development, both in terms of individual and family-level factors, and also higher-level influences, such as changing policies and social norms related to violence and abuse.[19 20] Longitudinal data collection yields important information on factors which may form part of the causal chain leading to favourable/unfavourable outcomes. Such studies provide essential evidence for prevention knowledge and policy-making.[21–23] For example, longitudinal studies in Jamaica have found that limited stimulation of children in the home and high levels of parental stress are negatively related to child outcomes, including cognitive function and behaviour.[23] These findings guided the development of Jamaica's National Parenting Policy, public messaging and programmes for parents.

Third, EBLS-FR addresses the lack of longitudinal studies examining violence in LMICs with analogous sampling and measurement to allow comparisons across locations.[24] Without the comparable methods used for longitudinal data collection in multiple settings, it is difficult to make cross-cultural comparisons of associations between exposures and outcomes.[25] Furthermore, although it is widely accepted that a fetus is influenced by the environment from conception and that the period from conception to age 2 to 3 is critical for development,[26] few cohort studies in LMIC have started in pregnancy.[27]

Fourth, a distinctive component of EBLS-FR is to engage fathers and male partners of the participants and learn more about how they can be motivated to participate in research. Extant research has linked father involvement in parenting to a number of crucial child outcomes, such as better infant cognitive development, more positive relationships with peers, better psychosocial adjustment as well as greater academic achievement.[28] Conversely, psychiatric disorders and violent behaviour of fathers, both inside and outside the family, can increase the risk of psychological and developmental difficulties in children.[29–31] While birth cohort studies report lower participation rates in fathers than mothers, they have also traditionally invested less in the recruitment and retention of fathers.[27 32 33] Hence, EBLS-FR recruits fathers in two sites, to gain further insight into engaging them in developmental research as well as to run an initial examination of the fathers' characteristics and their associations with maternal and child well-being.

In sum, a multi-country birth cohort study in LMICs, such as the planned EBLS, has major potential to influence local and international policies to prevent exposure to violence. It may also provide invaluable opportunities for knowledge transfer by promoting inter-country and global learning about how families and communities in different societies support their children to achieve their full developmental potential. EBLS-FR serves as a critical step towards generating such evidence for violence prevention and the promotion of healthy early child

development by testing rigorous and comparable ways to collect multi-country longitudinal data starting from pregnancy.

STUDY AIMS

This protocol outlines the motivation and methods for the EBLS-FR, developed as a pilot to inform EBLS, and examines the key uncertainties in the project design.[34 35] The aims of the EBLS-FR are:

1. To develop and test strategies for recruiting pregnant women and following them up during the perinatal period across eight EBLS-FR sites.
2. To assess the feasibility of fathers' and male partners' participation in the study.
3. To test the strategies to collect, manage and analyse comparable high-quality data across the eight EBLS sites, including questionnaires and biological samples.
4. To produce initial sample prevalence estimates of key indicators, such as prenatal exposure to violence, women's levels of well-being, stress, depressive symptoms, prenatal and perinatal complications and to describe the characteristics of their male partners.
5. To explore associations of the key indicators reported by mothers and fathers with maternal and birth outcomes.
6. To build and strengthen local capacity for longitudinal research by coordinating skill development opportunities and establishing local and international collaborative networks that include early career researchers.
7. To enhance engagement with policymakers, community members and other stakeholders and ensure that future stages of EBLS produce relevant knowledge and strategies to support efforts to address violence against children in all study sites.

DESIGN

EBLS-FR is a prospective birth cohort study that targets 1200 pregnant women (150 in each of the sites) and 300 fathers (150 in each of two sites) in different cultural contexts across the world. Measurements are carried out during the third trimester of pregnancy and when the child is aged 2 to 6 months.

Study settings

Participating sites were selected according to the following criteria: (1) country status of a low-middle and upper-middle income economy,[36] (2) representation of different regions of the world, (3) a political environment receptive to research-based evidence, (4) the presence of local research teams with the expertise and willingness to conduct comparative research and engage in advocacy based on the findings and (5) existing links of the research teams with local prenatal healthcare services to facilitate access to the target sample. In 2017, the participating sites and associated research teams were decided as follows (figure 2): Valenzuela (University of the Philippines, Philippines), Hue (Hue University, University of Medicine and Pharmacy, Vietnam), Ragama (University of Kelaniya, Sri Lanka), Tarlai Kalan (Health Services Academy, Pakistan), Cluj-Napoca (Babes-Bolyai University, Romania), Worcester (Universities of Cape Town and Stellenbosch, South Africa), Koforidua (University of Ghana, Ghana) and Kingston (University of the West Indies, Jamaica).

Figure 2 Evidence for Better Lives Study sites.

The sites were chosen to reflect the heterogeneity of social and cultural conditions across major world regions: the Caribbean, Europe, sub-Saharan Africa, the Indian subcontinent and South-East Asia. An overview of several international indices provides an account of such diversity (table 1). For instance, a comparison of the homicide rates in each site (ie, rate of intentional homicide per year per 100 000 inhabitants), suggests that while Romania, Sri Lanka and Vietnam report rates under the global average (6.4 per 100 000 population), Jamaica displays a rate of violence almost seven times higher than the global average.[37] The Gender Inequality Index shows that Vietnam and Pakistan report the lowest and the highest rates of inequalities, respectively, in reproductive health, education, political representation and access to the labour market.[38] Variation is also observed in other cross-comparative indexes such as Gross Domestic product (GDP), crude birth rates and percentage of population aged 0 to 14 years.

Capturing this diversity across the sites is critical for establishing how similar (and therefore generalisable and universal) the conditions are that lead to violence against women and children in different countries, and for demonstrating the consistency of their impact on children's long-term development. It is also crucial for understanding the cultural, contextual and policy factors that may lead to differences in risk of violence, and its adverse effects on child development. The diverse samples also offer opportunities to identify site-specific features that may be protective.[39]

Sampling strategy

Based on the time and resources allocated for this project, the decision was taken to use convenience sampling of participants within sites—a non-probabilistic strategy that allows a consecutive selection of participants in order

Table 1 Evidence for Better Lives Study sites: selected country indicators

	Homicide rates[a]	Gender Inequality Index[b]	GDP in $ (PPP)[c]	Crude birth rate[d]	% population aged 0 to 14[e]
Philippines	14.8	.425	8,908	21	30
Vietnam	3.8	.314	8,041	17	23
Sri Lanka	3.0	.380	13,078	16	24
Pakistan	9.6	.547	4,690	28	35
Romania	1.6	.316	29,909	10	16
South Africa	33.1	.422	12,482	21	29
Ghana	9.7	.541	5,413	29	37
Jamaica	39.1	.405	9,761	16	24
Global	6.4	.439	16,944	18	26%

Sources: a.[37]; b.[38]; c.[66]; d. [67]; e.[68].
*Abbreviation: GDP in $ (PPP). Gross Domestic product at purchasing power parity.
PPP, purchasing power parity.

of appearance.[40] Since we aim to achieve a sample that involves diverse social backgrounds within the study area, each local team attempts to target a specific number of private and public prenatal medical services, when these exist.

Study participants

Pregnant women

The EBLS-FR sample is comprised of 150 pregnant women recruited from health centres in each of the eight sites (n=1200 total). All women attending check-ups in the selected clinics/hospitals are eligible if they satisfy the following three criteria: (1) in the third trimester of their pregnancy (ie, weeks 29 to 40), (2) aged over 18 when signing the informed consent form and (3) having their main residence within the study's defined geographical area.

Fathers

Due to resource constraints, only two sites have the capacity to test the father's questionnaire. Sri Lanka and the Philippines plan to recruit a sample of 150 fathers each (n=300 total). All women who consent to participate in EBLS-FR in Sri Lanka and the Philippines are asked about the possibility of their husband or partner participating in the study. To be eligible, fathers need to meet the following three criteria: (1) being the father figure to the baby, although not necessarily the biological father; (2) aged over 18 when signing the informed consent and (3) having their main residence within the study's defined geographical area.

Recruitment, screening, consent and incentives

Recruitment

Trained female fieldworkers approach pregnant women directly at local health services during antenatal check-ups. When the direct approach is not feasible, potential participants are first approached by the treating clinician (eg, nurse, midwife, obstetrician), who briefly presents the research project and asks the woman if she is willing to meet with EBLS-FR representatives. Fathers are invited to take part in the study only if the pregnant woman provides written consent to their inclusion. Note that as p-IPV is a risk factor for under-utilisation of and delayed entry into antenatal care, our recruitment through antenatal clinics is a limitation, in that it risks under-representing women experiencing abuse.[41]

Screening and consent

Pregnant women and fathers expressing interest in the EBLS-FR are invited to answer a brief screening questionnaire to establish their eligibility. If eligible, they are invited to provide written informed consent. Information sheets, consent forms and questionnaires have been translated into the languages spoken by the participants. If the participant cannot read, versions of the information sheet and consent forms are played by audio recording or read out aloud. As suggested by the WHO's Research Ethics Committee (http://www.who.int/rpc/research_ethics/Process_seeking_IF_printing.pdf), the consent of participants who cannot write is obtained via alternative means (eg, audio recording or participant's thumbprint). The number of eligible participants who are approached but do not show interest in the study is also recorded, along with any reasons for non-participation, if provided.

When both the woman and her husband/partner participate, they are interviewed separately to ensure confidentiality.[42]

Incentives

All study participants are offered a token of appreciation. Each local team determines the specific incentive in consideration of cultural and local expectations, as well as the corresponding ethical rules (table 2). In all cases, the incentive is approximately equivalent to the hours spent in the study, reimbursed at minimum wage in the site. In addition, participants are offered a reimbursement of

Table 2 Incentives for participants

Sites	Incentive Baseline	Cost (£)	Incentive Follow-up	Cost (£)	Incentives for fathers	Cost (£)
Philippines	Groceries	2	Groceries	2	Groceries	2
Vietnam	Voucher	5	Voucher	5	N/A	N/A
Sri Lanka	Grocery voucher	4.78	Bank deposit for the baby	4.56	Grocery voucher	4.78
Pakistan	Household items for the woman	2.5	Jumper suit for the baby	2.5	N/A	N/A
Romania	Grocery vouchers	27	Grocery vouchers	10	N/A	N/A
South Africa	Grocery voucher	9	Grocery voucher	9	N/A	N/A
Ghana	Money	2.78	Money	2.78	N/A	N/A
Jamaica	Phone cards	4.26	Phone cards	4.26	N/A	N/A

Differences in cost are explained by their gross domestic product per capita at nominal values.[66]
*N/A: Not applicable.

travel expenses to facilitate the access of participants who could be underrepresented due to difficulties in paying for transport.[43 44]

Patient and public involvement

No patients will be involved. Study participants will be informed about study outcomes via websites of project partners and media reports. We are planning to produce a brief information sheet at the end of the foundational research for participants and a general audience.

Data collection

Data collection will be implemented from February to December 2019. To ensure comparability of measures across the sites,[45] the EBLS-FR team has developed a set of standardised questionnaires.

The EBLS questionnaires were first developed in English and then translated into nine different languages (Urdu, Afrikaans, IsiXhosa, Romanian, Filipino (Tagalog), Sinhala, Tamil, Vietnamese and Twi). With small modifications, the process of translation has followed the guidelines suggested by the WHO (http://www.who.int/substance_abuse/research_tools/translation/en/). Only minor adjustments have been made to ensure that measures are relevant in each location (eg, which ethnicities are recorded).

Data are collected by fieldworkers who have received standardised 40 hours of in-person training covering topics such as recruitment, consent, data collection and storage procedures, principles of research ethics, referral procedures and management of risk and difficult situations in the field (eg, participant distress or unsafe situations). Special emphasis was given to skills and strategies for addressing women experiencing violence.[46–48] The contents of the training were developed and approved by the EBLS consortium and they are described in the fieldworker handbook specifically developed for EBLS-FR. Training at each site was carried out by the local research coordinator who had been previously trained by the Cambridge team.

Pregnant women: questionnaires and instruments

Questionnaire

The questionnaire completed by pregnant women is a mix of Computer-Aided Personal Interviews (CAPI) and Computer-Assisted Self-Interviewing (CASI) for the more sensitive items (ie, intimate partner violence, adverse childhood experiences and substance use). To facilitate access for expectant mothers with low levels of literacy, Audio-Supported Self-Completion Interviewing (A-CASI) has been programmed.

In EBLS-FR, data from participating women are collected at two time points. The baseline assessment is completed when the women are in the third trimester of their pregnancy. The baseline assessment takes approximately 120 min, involving the completion of a 210-item questionnaire and the collection of biological samples. Subsequently, a brief follow-up assessment is conducted with the mother when the child is at least 2 months old. The follow-up assessment takes approximately 20 min and involves the completion of a 22-item questionnaire. The follow-up assessment re-measures key variables for the EBLS-FR such as mental health and mother-child attachment. It also helps to test the process of re-contacting participants and retaining them post-birth. The nature of a pilot study has restricted the follow-up to a maximum of 6 months after birth. However, the main study is expected to follow participants during the first 5 years of life.

Measures

Measures for pregnant women include items on demographic factors, socioeconomic status, prenatal health and reproductive history, adverse childhood experiences, community and social support, p-IPV, mental health and other psychological traits, as well as prenatal maternal attachment to the unborn child. The follow-up measures

Table 3 Evidence for Better Lives Study-Foundational Research measures for mother's questionnaire

Measures	Sources	N° items	Phase	Data collection strategy
Demographics	DHS[69] MacArthur Scale of subjective social status[70]	27	Baseline	CAPI
Prenatal health	Adapted from: The South Asian Birth Cohort (START)[71] Millennium Cohort Study[72]	20	Baseline	CAPI
Attitudes towards physical punishment	Attitudes towards spanking[73]	5	Baseline	CAPI
Community characteristics	Community characteristics scale – Adapted[74]	20	Baseline	CAPI
Adverse childhood experiences	WHO 2009,[47] International ACE-IQ Questionnaire Adapted version[75]	19	Baseline	A-CASI
Intimate partner violence	WHO Multi-country Study on Women Health and Domestic Violence against Women[46]	13	Baseline	A-CASI
Partner supportiveness	Partner supportiveness/relationship scale[76]	4	Baseline	CAPI
Social support	Social support scale[77]	13	Baseline	CAPI
Well-being	WHO-5 Well-Being Index[78]	5	Baseline	CAPI
Depression	PHQ9[79]	9	Baseline and follow-up	CAPI
Suicidality	Suicidality item[80]	1	Baseline	CAPI
Stress	Perceived Stress Scale[81]	10	Baseline	CAPI
Aggression	The Brief Aggression Questionnaire[82]	12	Baseline	CAPI
ADHD symptoms	Adult ADHD symptoms-Adapted[83]	6	Baseline	CAPI
Self-control	Brief Self-Control Scale[84]	8	Baseline	CAPI
Substance use	Alcohol, Smoking and Substance Involvement Screening Test (ASSIST) – Adapted version WHO ASSIST Working Group[85]	9	Baseline	A-CASI
Pregnancy related beliefs	Prenatal Attachment Inventory – Revised[86]	18	Baseline	CAPI
Newborn health and well-being	Norwegian Mother and Child Cohort Study (MoBa)[87] Questionnaire for breastfeeding mothers[88]	8	Follow-up	CAPI
The mother's birth memories	The Birth Memories and Recall Questionnaire[89]	5	Follow-up	CAPI

A-CASI, Audio-Supported Self-Completion Interviewing; CAPI, Computer-Aided Personal Interview; CASI, Computer-Assisted Self-Interview.

collect data on mothers' mental health, child well-being and birth memories (table 3).

Informed by a literature review developed by the EBLS consortium,[11] we have identified salient factors that may relate to the predictors and consequences of exposure to violence in the perinatal period. For reasons of space, we simply describe below the main measures used to capture these factors.

Prenatal intimate partner violence

p-IPV is measured using a scale extracted from the WHO's multi-country study on women's health and domestic violence against women.[46] It measures exposure to violence during the last 6 months (ie, current pregnancy). We use six items to capture physical violence (eg, I was hit with a fist or something else that could hurt); four items to measure emotional abuse (eg, I was insulted

or made to feel bad about myself); and three items for sexually abusive behaviours (eg, I was physically forced to have sexual intercourse when I did not want to). A 4-point Likert scale (ie, *never, once, a few times, many times*) allows the participant to report the frequency of exposure to such experiences in her lifetime and over the last 6 months. Questions have been validated in multi-racial, ethnic populations and in pregnant women and therefore have appropriate psychometric properties.[49 50] Exposure to p-IPV is collected using A-CASI as this approach has been demonstrated to facilitate the disclosure of IPV when compared with face-to-face interviews and self-administered written screens.[51 52]

The Perceived Stress Scale

The Perceived Stress Scale (PSS), developed by Cohen and Williamson,[53] was designed to measure the degree to which respondents appraise aspects of their own life experiences as unpredictable, uncontrollable and emotionally overwhelming. The scale includes 10 items (eg, feeling one could not cope with all the things that one had to do) and responses are provided using a 4-point Likert scale (ie, *not at all, several days, more than half the days, nearly every day*). The PSS has superior psychometric properties when used with a normative population, when compared with alternative scales and also when administered to pregnant mothers.[54 55]

Hair samples

Each pregnant woman is asked to provide a sample of hair cut from the posterior vertex area (where growth rates are least variable), as close as possible to the scalp. Hair samples produce measures of cortisol concentrations, an index of accumulated stress exposure validated for use in pregnant women.[56] Since each centimetre of hair represents a month's period of exposure, it is possible to quantify cumulative physiological stress during the second trimester of pregnancy. Previous research has suggested the second trimester of pregnancy in particular as a critical period for stress exposure.[9]

Blood samples

Dried blood spots are collected by applying a few drops of blood, drawn by lancet from a finger, onto medical-grade, absorbent filter paper. Blood samples are analysed for C-reactive protein (C-RP), a biomarker of inflammation. We will relate these biomarkers to information on violence exposure and maternal outcomes in order to illuminate the biological mechanisms underpinning the effects of violence and adversity exposure on maternal and birth outcomes.[57–59]

Father questionnaires

Data are collected using a paper and pencil questionnaire at two different time points. As in the case of pregnant women, the baseline assessment is completed during the third trimester of the woman's pregnancy. Interviews take approximately 40 min, involving the completion of a 90-item questionnaire. The follow-up assessment encompasses 37 items to be completed in about 20 min.

Measures

The father questionnaire requests information on demographic factors, socioeconomic status, adverse childhood experiences, partner support, mental health, psychological traits and substance use. These items are similar to those used in the mother's questionnaire. However, the father questionnaire includes some specific items measuring attitudes to fatherhood, participation in antenatal care visits and the father's participation in household activities.[60–62] The follow-up assessment asks the participant to complete items on paternal attitudes, paternal enjoyment and paternal confidence after birth (table 4).

Data analysis

Descriptive statistics will include frequency of p-IPV, and associations between exposure to violence and the putative outcomes (eg, C-RP, childbirth weight, maternal mental health). At the same time, candidate mediators and moderators in exposure-outcome associations will be explored. We will conduct measurement invariance analysis and make comparisons on latent variables across the sites. Statistical techniques will thus include linear and generalised linear models, structural equation models and multi-group item response theory and/or factor models. When data from multiple sites are used, multilevel models or multi-group models will be used to take account of the nested structure of the data. If available, EBLS-FR data will be compared with prevalence in the population. For instance, frequencies of IPV, perinatal depression and levels of stress or substance use will be compared with the prevalence of the same risk factors in the city's population. For the sites that conduct father interviews, models such as actor-partner interdependence models will be used to illuminate the influences of partners on one another's mental health, well-being and parental behaviour.[63]

All primary analyses will be pre-registered using open-access resources, such as the Open Science Framework (https://osf.io/). After a period of embargo, data will be available for the use of the international scientific community. Local stakeholders will be consulted to prioritise additional research questions to be answered with the data.

Ethics and dissemination

The EBLS-FR protocol for recruitment and collection of data has been approved by the Ethics Boards of all universities involved in the project (see section declarations for more detail). Results will be disseminated through journal publications, conferences and seminar presentations involving local communities, health services and other stakeholders.

Table 4 Evidencef or Better Lives Study-Foundational Research measures for father's questionnaire

Measures	Sources	N° items	Phase	Data collection strategy
Feelings about fatherhood (prenatal)	Adapted from the Avon Longitudinal Study of Parents and Children[60]	13	Baseline	Paper and pencil
Fathers' participation for antenatal care	[61 62]	7	Baseline Follow-up	Paper and pencil
Fathers' participation for household activities	Adapted from the Avon Longitudinal Study of Parents and Children.	8	Baseline Follow-up	Paper and pencil
Attitudes to fatherhood	Avon Longitudinal Study of Parents and Children[60]	8	Follow-up	Paper and pencil
Paternal enjoyment	Avon Longitudinal Study of Parents and Children[60]	5	Follow-up	Paper and pencil
Paternal confidence	Avon Longitudinal Study of Parents and Children[60]	4	Follow-up	Paper and pencil
Activities with the newborn child	Avon Longitudinal Study of Parents and Children[60]	6	Follow-up	Paper and pencil

Confidentiality and data protection

In EBLS-FR all participants are assigned a numeric identification (ID) code. The personally identifiable data, including contact details, are kept separate from all data collected via questionnaires to ensure confidentiality. EBLS-FR uses a number of technical and organisational measures to maintain security, confidentiality, completeness and integrity of the data associated with the study. This includes adherence to the requirements on collection and processing of personal identifiable data as stipulated by the General Data Protection Regulation (GDPR) EU 2016/679.

Data quality and data management

Multiple strategies are used to enhance the quality of data collection. These include training of project workers in the administration of questionnaires, training of clinical and project staff in the measurement of specific indices, and validation checks for consistency and completeness of routinely collected data. Laboratory analyses will be subject to strict quality controls based on established protocols. Data will be screened for out-of-range or otherwise implausible values before finalising the data set.

Organisational structure

EBLS comprises a consortium of 15 co-investigators who are collectively responsible for conducting the research. Given the multidisciplinary nature of violence and its impacts on child development, the team includes expertise in disciplines such as developmental psychopathology, paediatrics, criminology and public health. The organisational structure includes a coordinating team at the University of Cambridge. In each of the sites, a collaborative research team has been established to implement the EBLS-FR study.

DISCUSSION

Ending violence against children, dealing with its consequences, and reducing children's exposure to threats to their healthy development, requires a better understanding of the factors that foster child development in various societies and the identification of risk factors that need to be addressed most urgently. EBLS is designed to make novel contributions to these key questions by drawing on parallel data collection in eight sites, thus enabling both within-country and cross-country analyses. While the experience of conducting the EBLS-FR will illuminate the feasibility of procedures for the next stages, psychometric analyses will provide empirical information on the cross-cultural performance of the study's measures. Analyses of the EBLS-FR data will also provide initial estimates of the levels of exposure to adversity and the relationships between exposures and outcomes, as well as test potential pathways and moderating factors.

Conducting research in multiple regions will allow us to examine how findings generalise across different socio-cultural and political contexts. To complement participants' reports of their experiences and behaviours, the study will also include biological data collection to examine biological pathways related to violence and health. This will allow us to test for the first time the combined role of systemic inflammation and the HPA axis on mediating links between p-IPV and maternal and birth outcomes. It has been argued that highlighting the biological effects of social issues (such as violence) can be particularly effective in motivating policy change.[64] EBLS-FR data collection tools and data sets from eight countries can also benefit the broader research community working on violence prevention.

EBLS-FR has also been designed to foster strategic collaborations, knowledge exchange and capacity

building between researchers, communities and policymakers in order to link research findings to policy actions. Future stages of EBLS will reveal the extent and manifestations of exposure to violence in each site; they will identify the salience of risk and protective factors for different groups and contexts; they will alert decision-makers to the short-term and long-term consequences of violence against women and children that are not currently addressed; and they will establish the essential basis for future actions. Such knowledge exchange between researchers and governments is essential to establish and evaluate prevention efforts and report on progress toward Sustainable Development Goal (SDG) violence reduction targets.[65]

Conducting a multi-site project poses both research design and management questions of how to maintain comparability across countries while also examining relevant issues that are only present in some of the contexts, such as child marriage. As reflected in the organisational structure of the study, we believe that multi-country, multidisciplinary projects require both a strong level of international coordination and collaboration with local governance structures.

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